

JUN 27 2006

K060848
PAGE 1 OF 2

Section 5 – 510(k) Summary

The following is the 510(K) summary in accordance with 21CFR807.87(h)

SUBMITTER INFORMATION

<u>Company Name:</u>	Life Measurement, Inc.
<u>Establishment Registration Number:</u>	3003873943
<u>Company Address:</u>	1850 Bates Avenue Concord, CA 94520
<u>Company Phone:</u>	(925) 676-6002
<u>Company Facsimile:</u>	(925) 676-6005
<u>Contact Person:</u>	Michael Sullivan Vice President of Operations

DEVICE IDENTIFICATION

<u>Device Trade Name:</u>	Sonamet Body Composition Analyzer Note : The trade name for the original Sonamet Body Composition analyzer is currently the “BOD POD”. This will remain unchanged.
<u>Device Generic Name:</u>	Body Composition Analyzer
<u>Device Classification:</u>	Classification code: 21 CFR 870.2770 Code MNW
<u>Classification Panel</u>	Cardiovascular

IDENTIFICATION OF PREDICATE DEVICES

The Sonamet Body Composition System is substantially equivalent to the following devices, which have received FDA clearance:

Device Name	Manufacturer	K Number
Sonamet Body Composition Analyzer	Life Measurement, Inc.	K924972
TANITA Segmental Body Composition Analyzer Model BC-418	TANITA Corporation of America	K033157

The technological characteristics of the Sonamet Body Composition System have not been changed. The method of calculating RMR using values of Fat Free Mass and Fat Mass is similar to the methods used by the TANITA Model BC-418 unit to calculate Basal Metabolic Rate.

DEVICE DESCRIPTION

The Sonamet Body Composition System is designed to measure the mass and estimate the body composition of individuals. Once an individual's body composition has been determined, the BOD POD is able to accurately estimate Resting Metabolic Rate (RMR) and total Energy Expenditure (TEE).

The BOD POD estimates body composition using a densiometric approach (i.e. by determining the density of the entire body). A weighing apparatus is used to measure the subject's mass. Air displacement plethysmography is used to measure the subject's volume. Using this data, the subject's density is calculated. The subject's body composition is then estimated using several algorithms derived from scientific research.

An individual's RMR and TEE can also be estimated accurately using values for Fat Mass and Fat Free Mass. Scientifically derived algorithms utilize the Fat Mass and Fat Free mass values determined by the BOD POD to calculate RMR and TEE.

INTENDED USE

The BOD POD® is indicated for measuring the body mass and estimating the body composition (i.e. percent and absolute amounts of fat and lean body mass) of generally healthy individuals. The BOD POD is also indicated for estimating Resting Metabolic Rate (RMR) and Total Energy Expenditure (TEE) in generally healthy individuals aged 18 years or older.

CONCLUSIONS DRAWN FROM STUDIES

The results of verification testing demonstrate that the RMR and TEE results generated by the BOD POD Body Composition Analyzer are accurate when compared with expected results based on published scientific research, and is substantially equivalent to the predicate devices. Test results indicate that the device satisfies functional performance requirements safely and accurately when used as indicated.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 27 2006

Mr. Alex Urlando
Vice President, Operations
Life Measurement, Inc.
1850 Bates Avenue
CONCORD CA 94520

Re: K060848

Trade/Device Name: BOD POD® Sonamet Body Composition Analyzer [modified indications]

Regulation Number: 21 CFR §870.2770

Regulation Name: Impedance plethysmograph

Regulatory Class: II

Product Code: MNW

Dated: March 23, 2006

Received: March 31, 2006

Dear Ms. Urlando:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must still comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits you to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0113
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0113
21 CFR 894.xxx	(Radiology)	240-276-0113
Other		240-276-0113

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.htm>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060848

Device Name: Sonamet Body Composition Analyzer (BOD POD)

Indications For Use:

The BOD POD® is indicated for measuring the body mass and estimating the body composition (i.e. percent and absolute amounts of fat and lean body mass) in generally healthy individuals. The BOD POD is also indicated for estimating Resting Metabolic Rate (RMR) and Total Energy Expenditure (TEE) in generally healthy individuals aged 18 years or older.

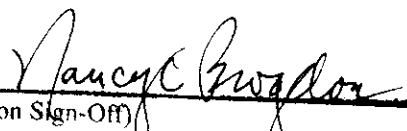
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801.10)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON REVERSE IF MORE SPACE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (10/1/05)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060848

(vers 6/25/05)

Page 1 of _____